IPI Academy

MANAGEMENT forum

*Presented by*
**Management Forum**

# Understanding Active Pharmaceutical Ingredients (APIs)

**16-17 July 2025**
+ 19-20 November 2025

This course will cover key terminology, the EU and USA regulatory framework, Good Manufacturing Practice (GMP) requirements including controls and validation, and consider Good Distribution Practice (GDP) and how to manage your supply chain.

**Format:**
Live online

**CPD:**
12 hours for your records

Certificate of completion

# Course overview

**An active pharmaceutical ingredient (API) or drug substance is any substance or mixture of substances intended to be used in the manufacture of a medicinal product,** which is intended to furnish pharmacological activity, or have another direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or affect the structure and function of the body.

This course has been designed to provide attendees with a fundamental understanding of best practice and the regulatory environment applicable to active pharmaceutical ingredients in the pharmaceutical industry. It will cover key terminology, the EU and USA regulatory framework, Good Manufacturing Practice (GMP) requirements including controls and validation, and consider Good Distribution Practice (GDP) and how to manage your supply chain. Practical exercises will form part of the course to aid the learning process.

This is an essential and valuable introduction to the manufacture of APIs.

## Benefits of attending

- **Gain** a comprehensive overview of the API regulatory framework
- **Enhance** your understanding of the key terms used in API manufacture
- **Recognise** how Good Manufacturing Practices (GMP) apply to API synthesis
- **Understand** the different approaches between small molecule and large molecule processing
- **Learn** how to manage the risk associated with your supply chain

## Who should attend?

- New entrants to those individuals working in a GxP environment
- Quality management manufacturing specialists
- Regulatory compliance specialists
- Pharmaceutical technical professionals
- Pharmaceutical professionals looking to enhance their Continuous Professional Development (CPD)

# Programme

## Day 1

**Introduction to APIs**

- Terminology and acronyms
- Globalisation
- Introduction to the regulatory framework

**Methods and equipment – Part 1**

- Chemical synthesis
- Reactors
- Isolation
- Drying
- Exercise: managing particle size

**Methods and equipment – Part 2**

- Biological
- Fermentation
- Harvesting
- Exercise: impurities

**Good Manufacturing Practice (GMP)**

- Requirements
- Regulations
- EU
- FDA
- Exercise: similarities and differences

**GMP requirements (continued)**

- Pharmaceutical Quality System
- Validation and Qualification
- Outsourcing
- Exercise: specialist or generalist

**Supply chain considerations**

- Falsified Medicines Directive (FMD)
- Good Distribution Practice (GDP) for APIs
- Exercise risk mitigation

## Day 2

**Introduction and recap**

**Registration aspects of production and control**

- The registration process
- The Common Technical Document (CTD)
- Active substance/drug master files
- Exercise: strategy

**Laboratory controls**

- Good Quality Control Laboratory Practice (GQCLP)
- Validation
- Stability
- Exercise: data Integrity

**Process validation**

- Purpose of validation
- General considerations
- Exercise: critical attributes

**Cleaning validation**

- Cleaning strategy
- Key requirements
- Residues
- Exercise: purpose

**API control packaging materials**

- What to consider
- Data requirements
- Extraction, interaction, migration and sorption
- Toxicology
- Exercise: environmental factors

**Wrap up and Q&A**

# Presenters

**Paul Palmer**

16-17 Jul 2025
19-20 Nov 2025

Paul R Palmer is a Director / Pharmaceutical Consultant and a practicing EU / UK Qualified Person. He has over 35 years experience in the pharmaceutical industry in the development, manufacture and supply of medicinal products and medical devices.

Throughout his career, Paul has intentionally taken on all opportunities as they arose in order to develop a broad range of knowledge with an in-depth detailed understanding of manufacturing, storage, distribution, research, computerised systems, as well as the facilities and services to support each.

People and systems have always been a core focus, how to ensure best use, optimise and enhance efficiency. He has a level of curiosity rarely displayed in people taking on the qualified person role in pharmaceutical manufacturing. Culture, behaviour and psychology are all significant influences on the systems and processes we implement, but are often ignored.

Paul studied psychology as part of his MSc in 1993 and has always enjoyed observing the world around him with a curiosity that is rarely satisfied.

**Farah Nadeem**

16-17 Jul 2025

Farah Nadeem is an Operations Manager at Paul R. Palmer Limited/ Pharmaceutical Consultant and a Trainee Qualified Person. Farah is a Pharmacist and recognised QA expert and has over 20 years of experience in the Pharmaceutical industry in the development, manufacture and supply of medicinal products.

Throughout her career, she has held various quality assurance roles and actively pursued new opportunities to expand her knowledge and expertise. As a result, she has gained a comprehensive understanding of manufacturing, storage, and distribution processes, as well as the facilities and services that support them. Involved in documentation management: writes, reviews, and audits SOPs and QMS implementations. Assists companies in meeting regulatory requirements.

In her current role as a QA Operations Manager for a Pharmaceutical Consultant Company, Farah Nadeem provides various solutions, including assistance in obtaining the first MIA(IMP) and MIA licenses, as well as preparation and hosting for regulatory inspections. Her work involves collaborating with Paul Palmer to offer services such as QP declarations for API manufacturers, regulatory inspection hosting, commercial and clinical batch release, compliance audits, and coaching and training in GxP.

# Course dates

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|---|---|---|
| **16-17 July 2025** | **Live online**<br>09:30-17:30 **UK (London)** (UTC+01)<br>*Course code 14849* | GBP **1,499**<br>EUR **2,099**<br>USD **2,399** |
| **19-20 November 2025** | **Live online**<br>09:30-17:30 **UK (London)** (UTC+00)<br>*Course code 15073* | GBP **1,299** ~~1,499~~<br>EUR **1,819** ~~2,099~~<br>USD **2,087** ~~2,399~~<br>**Until 15 Oct** |

## How to book

**Online:**
ipi.academy/2505

Alternatively contact us to book, or if you have any queries:

**Email:**
info@ipiacademy.com

**Phone:**
+44 (0)20 7749 4749

## Discounts

- Booking more than one delegate on any one date qualifies for a **30% discount** on the second and subsequent places.
- Most events qualify for an **early booking discount** prior to 6 weeks before the course date. Be sure to check on our website, where the latest discounts will be shown.

## Further information

**Fee**
The fee includes all meals and refreshments for the duration of the course (for venue-based courses) and a complete set of course materials (provided electronically). If you have any particular requirements, please advise customer services when booking.

**Please note**
IPI Academy (and our training partners) reserve the right to change the content and timing of the programme, the speakers, the date and venue due to reasons beyond their control. In the unlikely event that the course is cancelled, we will refund the registration fee and disclaim any further liability.

**Terms and conditions**
The rest of the our terms, the event cancellation policy and the terms and conditions are on our website, please visit ipi.academy/content/terms-and-conditions

## Run this programme in-house for your whole team

Coming to IPI Academy for your in-house training provides an all-inclusive service which gives you access to a wide variety of content, learning platforms and delivery mechanisms as well as your own personal training adviser who will work with you from the initial enquiry through to feedback and follow-up after the programme.

With over 600 trainers, all practitioners and experts across a huge range of fields, we can provide the training you need, where you need it, when you need it, and at a price which suits your budget. Our approach to tailored learning and development consists of designing and delivering the appropriate solution for each client.

For your FREE consultation and to find out more about how we can work with you to solve your training needs, please contact our training advisers:

**ALEKSANDRA BEER**
**Tel:** +44 (0)20 7749 4749
**Email:** inhouse@ipiacademy.com

**YESIM NURKO**
**Tel:** +44 (0)20 7749 4749
**Email:** inhouse@ipiacademy.com

IPI Academy

IPI Academy is a training initiative of Falconbury and Management Forum; leading providers of industry training for over 30 years, based in the UK.

10-12 Rivington Street
London EC2A 3DU

ipi.academy
**Tel:** +44 (0)20 7749 4749
**Email:** info@ipiacademy.com